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| 10/031,222 | 06/04/2002 | Hermanus Johannes Maria Kreuwel | 9310-38 | 2628 |

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EXAMINER

LUDLOW, JAN M

| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 03/20/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,222

Applicant(s)

KREUWEL ET AL.

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1743

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. Claims 1-15 are objected to because of the following informalities: In claims 1 and 6, "at least one magnets" should be "at least one magnet" for grammatical clarity. Device claims 7-15 depend from method claim 1. For purposes of examination, they

Art Unit: 1743

have been treated as depending from claim 6. In claim 16, part m, "container" should be "contained". Appropriate correction is required.

3. Claims 1-5, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "intervening array geometry" is unclear. In claim 13, "closed system" is unclear.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1743

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-4, 6, 9, 11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakazume et al.

Sakazume teaches a method and apparatus for immunoassay by mixing magnetic particles in containers 1 using magnets 27 with like poles facing one another in an array, with a linear array of containers "intervening" (Figures 8 and 9). The containers are moved as shown by the arrows to provide a varying magnetic field (e.g., col. 2, lines 16-17). The system is "closed" in that the turntable provides a closed travel loop for the containers (col. 9, line 65).

9. Claims 5, 10, 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume as applied to claims 1-4, 6, 9, 11, 13 above, and further in view of WO 96/26011 (Kirchanski et al).

10. Sakazume fails to teach moving the magnets or nucleic acid isolation.

Art Unit: 1743

11. Kirchanski teaches a method and apparatus similar to that of Sakazume. Nucleic acids are taught as an alternative to antibodies in biospecific affinity reaction (p. 1, lines 8-24). Kirchanski further teaches that moving the magnets relative to a stationary container is an alternative to moving the containers relative to the magnets, see, e.g., Figures 1-4 and descriptions thereof.

12. It would have been obvious to one of ordinary skill in the art to configure the device of Sakazume to separate nucleic acids in a nucleic acid binding assay in order to test nucleic acids as an alternative to antibodies in a biospecific reaction as taught by Kirchanski. It would have been further obvious to move the magnets relative to the containers in order to provide an art recognized alternative to moving the containers past the magnets as taught by Kirchanski. With respect to claim 14, it would have been obvious to use conventional laboratory vessels, such as round bottom test tubes or microcentrifuge (Eppendorf) tubes for their known fluid containment purpose, such tubes having a smaller diameter at the bottom than at the top.

13. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume as applied to claim 6 above, and further in view of Tuunanen and Komai et al.

Sakazume fails to teach a moveable heater.

Tuunanen teaches a magnetic particle immunoassay device. A heater is provided for controlled temperature incubation (col. 5, lines 27-28).

Tuunanen fails to teach a moveable heater for individual tubes.

Art Unit: 1743

Komai et al teaches a magnetic separation device. A moveable heater for encapsulating the bottom of a tube is used for temperature control (col. 9, lines 29-30).

It would have been obvious to use a temperature controller in Sakazume in order to incubate immunoassays at controlled temperature as taught by Tuunanen. It would have been obvious to provide the heater in the form of a moveable block with indentations in order to surround individual tubes and remove when not in use as taught by Komai.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume as applied to claim 6 above, and further in view of Ammann et al and/or Howe et al.

Sakazume fails to teach means for moving the magnet in a vertical direction.

Ammann et al teach means for moving a magnet vertically to place it in, and remove it from, the position of use (Fig. 25).

Howe et al teach means for moving a magnet vertically to place it in, and remove it from, the position of use (Fig. 4A).

15. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the magnets of Sakazume vertically moveable in order to remove them from engagement with the tubes when not in use as taught by Ammann et al and/or Howe et al.

16. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Komai et al in view of Sakazume and Eddelmann.

Art Unit: 1743

Komai et al teach the method substantially as claimed, with the exception of the mixing method step (b) and moving the particles above the fluid step (I). See figure 10 and element 41.

The teachings of Sakazume are given above.

Eddelmann teaches lifting particles along the tube wall to remove from fluid to enhance separation (Figs. 7-12).

It would have been obvious to use the mixing method of Sakazume in the method of Komai in order to provide better mixing of magnetic particles in a fluid as taught by Sakazume. It would have been further obvious to lift the particles above the fluid level using the magnet in order to provide better separation as taught by Eddelmann.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Art Unit: 1743

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
March 19, 2003